

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

MARIUSZ MAZUREK, individually and on behalf of all others similarly situated,)	
)	
Plaintiff,)	Civil Action No.:
)	
v.)	<u>CLASS ACTION</u>
)	
SERES THERAPEUTICS, INC., ROGER J. POMERANTZ, and ERIC D. SHAFF,)	<u>DEMAND FOR JURY TRIAL</u>
)	
Defendants.)	
)	

COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS

Plaintiff Mariusz Mazurek (“Plaintiff”), by his attorneys, except for his own acts, which are alleged on knowledge, alleges the following based upon the investigation of counsel, which included a review of United States Securities and Exchange Commission (“SEC”) filings by Seres Therapeutics Inc. (“Seres” or the “Company”), as well as regulatory filings and reports, securities analyst reports and advisories by the Company, press releases and other public statements issued by the Company. Plaintiff believes that additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery:

NATURE OF THE ACTION

1. This is a securities class action on behalf of all persons who purchased Seres common stock between June 25, 2015 and July 29, 2016, inclusive (the “Class Period”), seeking remedies under the Securities Exchange Act of 1934 (the “Exchange Act”). Plaintiff’s claims are asserted against certain of Seres’s executive officers and directors.

2. Seres is a clinical stage biopharmaceutical company with a focus on microbiome therapeutics. The human microbiome is an ecology of microorganisms, including bacteria, fungi and viruses, that, when unhealthy, or dysbiotic, can leave the body more susceptible to infections, metabolic disorders, allergies, autoimmune disease, inflammation and other serious conditions. Thus, the Company's drugs are designed to restore health by repairing the function of a dysbiotic microbiome.

3. The Company's lead product candidate is SER-109, a clinical-stage oral microbiome therapeutic designed to prevent further recurrences of *Clostridium difficile* infection ("CDI"), a debilitating infection of the colon. CDI leads to severe and persistent diarrhea in infected individuals, but can also lead to more severe outcomes, such as inflammation of the colon, toxic megacolon and death. The U.S. Centers for Disease Control ("CDC"), has identified CDI as one of the top three most urgent antibiotic-resistant bacterial threats in the United States. If approved by the FDA, SER-109 would be, according to the Company, "a first-in-field drug."

4. Seres announced final data from its Phase 1b clinical trial of SER-109 on September 8, 2014. In the single-arm, open label study, the data demonstrated that SER-109 resulted in clinical cures, with 29 of the trial's 30 patients (97 percent) reaching the 8-week endpoint free of infection. According to the Company, the study also demonstrated that SER-109 is well-tolerated and has a favorable safety profile.

5. Based on the positive results from the Phase 1b clinical trial, the Company proceeded to a Phase 2 clinical trial in May 2015. The Phase 2 trial was structured as a multicenter, randomized, placebo-controlled study to further evaluate the efficacy and safety of SER-109. The primary outcome measure was the absence of clinically-significant CDI through eight weeks following administration of SER-109 compared to placebo. The first patient was

dosed in the Phase 2 trial on May 28, 2015, and patient enrollment in the trial was completed on May 2, 2016.

6. Since June 25, 2015, Seres and certain of its officers and directors have misrepresented: (i) the efficacy of SER-109, and attendant capacity for approval by the U.S. Food and Drug Administration (“FDA”); and (ii) the structure of the Phase 2 trial designed to further test the efficacy of SER-109. For example, these materially false and misleading statements included, among others, the following:

- “[W]e believe *[SER-109] will enable us to provide a more effective and safer treatment for preventing the recurrence of CDI than the current standard of care.*”
- “[W]e believe SER-109 could be a first-in-field drug.”
- “We have made significant progress this quarter to advance our mission of delivering Ecobiotic® microbiome medicines to patients, which *we believe will have a strong impact in multiple therapeutic areas.*”
- “With current treatment approaches having significant limitations, *SER-109 has the potential to fundamentally change the management of this urgent health issue.*”
- “In 2016 we anticipate several important milestones, including SER-109 Phase 2 results in recurrent CDI infection in mid-2016, the initiation of a Ph1b study for SER-262, a fermented synthetically derived therapeutic candidate, in primary recurrent CDI in mid-2016, and *the initiation of a Phase 3 study for SER-109 in recurrent CDI infection in the second half of 2016.*”

(Emphasis Added.)

7. On July 29, 2016, following close of market, Seres issued a press release announcing interim 8-week results from the Phase 2 clinical trial of SER-109. The Company disclosed that SER-109 had failed to reach its primary endpoint of reducing the relative risk of CDI recurrence at up to 8-weeks when compared to a placebo. Based on 8-week data, CDI recurrence occurred in 44 percent of subjects (26 of 59) who received SER-109, compared to 53

percent of subjects (16 of 30) who received placebo. According to the Company, the relative risk of CDI recurrence for the placebo population compared to the SER-109 population was not statistically significant.

8. On this news, the price of Seres common stock declined from a closing share price of \$35.77 on July 28, 2016 to close at \$9.73 per share on August 1, 2016, *a loss of more than 70%*, on extremely heavy trading volume.

JURISDICTION AND VENUE

9. The federal law claims asserted herein arise under §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78j(b) and § 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

10. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and § 27 of the Exchange Act, 15 U.S.C. § 78aa.

11. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and § 27 of the Exchange Act because many of the false and misleading statements were made in or issued from this District. Seres is headquartered in this District, with its principal place of business located at 200 Sidney Street, Cambridge, Massachusetts 02139.

PARTIES

13. Plaintiff Mariusz Mazurek purchased Seres securities as set forth herein and in his certification filed herewith.

14. Seres is a corporation organized and existing under the laws of the State of Delaware. The Company's common stock trades on the NasdaqGS ("NASDAQ") under the symbol, "MCRB."

15. Defendant Roger J. Pomerantz ("Pomerantz") is the President, Chief Executive Officer ("CEO"), and the Chairman of the board of directors (the "Board") of Seres.

16. Defendant Eric Shaff ("Shaff") is the Chief Financial Officer ("CFO") and Executive Vice President of Seres.

17. Pomerantz and Shaff are collectively referred to herein as the "Individual Defendants."

18. Seres and the Individual Defendants are collectively referred to herein as "Defendants."

CONTROL PERSON ALLEGATIONS

19. By reason of the Individual Defendants' positions with the Company as executive officers (and in Pomerantz's case, as a director) the Individual Defendants possessed the power and authority to control the contents of Seres's quarterly and annual reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company, and their access to material, non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the

public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

20. Seres is a clinical-stage biopharmaceutical company developing a novel class of biological drugs, which the Company refers to as Ecobiotic microbiome therapeutics. The human microbiome is an ecology of microorganisms, including bacteria, fungi and viruses, that, when unhealthy, or dysbiotic, can leave the body more susceptible to infections, metabolic disorders, allergies, autoimmune disease, inflammation and other conditions. Thus, the Company's drugs are designed to restore health by repairing the function of a dysbiotic microbiome.

21. Seres's lead product candidate, SER-109, is designed to prevent further recurrences of *Clostridium difficile* infection, or CDI, a debilitating infection of the colon. Seres announced final data from its Phase 1b clinical trial of SER-109 on September 8, 2014. The Phase 1b clinical study was designed to analyze the safety and efficacy profile of SER-109 for recurrent CDI at four study sites. Efficacy was assessed by the absence of CDI over an 8-week period, while safety was assessed by phone contact on day 4 and weeks 1, 2 and 4, and by in-person physical exams on weeks 8 and 24.

22. Further, the Phase 1b clinical study was structured to include two, 15-patient cohorts based on dosage received. In cohort 1, thirteen of the fifteen patients (87 percent) achieved the protocol-defined endpoint. In addition, two patients had transient, self-limited diarrhea with a positive *C. Diff* test, but both reached the week 8 endpoint without needing antibiotic therapy for CDI. Thus, in cohort 1, the clinical cure rate was 15 out of 15 (100

percent). In cohort 2, fourteen of the fifteen patients achieved the 8-week endpoint CDI free. One patient failed per protocol.

23. Based on data from the Phase 1b trial and discussions with the FDA, Seres initiated a Phase 2 clinical study of SER-109 for recurrent CDI and dosed the first patient in May 2015. The Phase 2 clinical study of SER-109 was structured to include 87 patients in a double-blinded and placebo-controlled clinical trial, with patients randomized in a ratio of 2:1 into a SER-109 arm or placebo arm. The primary endpoint of the trial was the absence of CDI recurrence requiring antibiotic treatment during the eight-week follow-up period after dosing. Secondary endpoints included the time to CDI recurrence and the proportion of patients experiencing CDI recurrence at four weeks, twelve weeks and twenty-four weeks.

24. In addition, subjects in the Phase 2 clinical trial that experienced a recurrence of CDI during the eight-week follow up period were afforded the option of enrolling in Seres's parallel open label extension study where they would be treated with a single dose of SER-109. An open-label trial is a type of clinical trial in which both the researchers and the patients know which treatment is being administered. Thus, each patient in the open label extension study was "unblinded" to the fact that they were receiving SER-109, and not a placebo.

25. Seres announced on May 28, 2015, that it had initiated patient enrollment in the Phase 2 clinical trial. According to the Company's press releases, Seres completed enrollment in the Phase 2 trial on or about May 2, 2016, and expected to have interim data in the middle of 2016, i.e. sometime between June and July 2016. Patients were enrolled in the open label extension study as they were unsuccessfully treated in the Phase 2 clinical trial.

Defendants' Material Misrepresentations and Omissions

26. On May 27, 2015, Seres filed a Form S-1 Registration Statement ("Registration Statement") with the SEC announcing its initial public offering ("IPO"). The Registration Statement was deemed effective by the SEC on June 25, 2015, the beginning of the Class Period. The Registration Statement touted the efficacy and outlook of Seres's lead drug candidate, SER-109, stating in relevant part:

In our recently completed open label Phase 1b/2 clinical study, 29 of 30 patients, or 97% of patients, achieved a clinical cure, which we defined as the absence of CDI requiring antibiotic treatment during the eight-week period after SER-109 dosing. Additionally, 26 of 30 patients, or 87% of patients, achieved the primary efficacy endpoint of experiencing no recurrence of CDI associated diarrhea during the eight weeks post-treatment. The study demonstrated a favorable safety profile with no serious adverse events considered by the investigators to be attributable to SER-109 treatment. Based on these results, we initiated a Phase 2 clinical study of SER-109 for recurrent CDI and dosed the first patient in May 2015. We expect study results in the middle of 2016. *We plan to conduct manufacturing process pre-validation studies of SER-109 in the second half of 2015 to support a Phase 3 clinical trial and a potential biologics license application and commercial launch.*

We believe the results of our open label Phase 1b/2 clinical study of SER-109 provide validation of the hypothesis underlying our microbiome therapeutics platform, supporting its further use to develop additional Ecobiotic microbiome therapeutics. Using the data we obtained from the SER-109 clinical trial, we are developing SER-262 as an Ecobiotic microbiome therapeutic designed to be used following antibiotic treatment of primary CDI to prevent the initial recurrence of CDI. SER-262 consists of bacteria that are a subset of the bacterial ecology comprising SER-109. Unlike SER-109, SER-262 strains are clonally isolated and produced in fermenters and do not require donations from human sources. Pre-clinical studies of SER-262 have demonstrated efficacy in preventing the recurrence of CDI in mouse and hamster models. We intend to initiate clinical studies of SER-262 in the middle of 2016.

If approved, we believe these two product candidates will enable us to provide a more effective and safer treatment for preventing the recurrence of CDI than the current standard of care.

(Emphasis added.)

27. The Registration Statement went on to describe SER-109 as “a novel approach with potential application across a broad range of human diseases.” The Registration Statement also stated, *inter alia*, the following:

Our Strategy

Our goal is to become the leading biopharmaceutical company developing and commercializing microbiome therapeutics to address significant unmet medical needs. The critical components of our strategy include:

Rapidly advancing the development of our lead product candidate, SER-109, for the prevention of further recurrences of CDI in patients with recurrent CDI. Based on the results from our recently completed Phase 1b/2 clinical study of SER-109, we dosed the first patient in a Phase 2 clinical study in May 2015 in patients with three or more occurrences of CDI within the previous nine months. We have an investigational new drug application, or IND, with the FDA for the Phase 2 clinical study. We expect to enroll 87 patients in a double-blinded and placebo-controlled clinical trial, with patients randomized in a ratio of 2:1 into a SER-109 arm or placebo arm. The primary endpoint of the trial will be the absence of CDI recurrence requiring antibiotic treatment during the eight-week follow-up period after dosing. We also plan to follow patients for an additional 16 weeks to document the safety profile of SER-109 compared to placebo. Secondary endpoints include the time to CDI recurrence and the proportion of patients experiencing CDI recurrence at four weeks, 12 weeks and 24 weeks. We also plan to compare changes in the composition of the colonic microbiome from baseline to Week 24 post-treatment using genomic analysis. In addition, subjects that recur in either arm of the study will have the option to enroll in a parallel open label safety study in which patients will receive SER-109. We expect results from the Phase 2 clinical study in the middle of 2016. Following the analysis of the data to come from our Phase 2 clinical study, we plan to meet with the FDA to present Phase 2 safety and efficacy results and a proposed protocol for the Phase 3 clinical trial. We plan to initiate the Phase 3 clinical trial in 2016.

Leveraging our leading microbiome therapeutics platform to develop additional innovative and novel Ecobiotic microbiome therapeutics across a range of medical conditions with high unmet need. We believe that the combination of experience, proprietary data and proprietary know-how related to the microbiome and of the production of microbial strains provides us a competitive advantage in the design and development of microbiome therapeutics. Our platform enables us to build upon our existing and growing clinical experience to rationally approach the treatment of acute and complex chronic diseases. We intend to leverage this advantage to develop additional innovative Ecobiotic microbiome therapeutics.

Commercializing our Ecobiotic microbiome therapeutics, including SER-109, directly in the United States and with collaborators outside the United States. We have retained the worldwide rights to SER-109 and SER-262 and expect to initially maintain

similar rights with respect to other Ecobiotic microbiome therapeutics we develop. We believe the market for recurrent CDI is sufficiently concentrated to permit us to effectively commercialize SER-109 in the United States with a direct sales force of less than 100 individuals. We intend to leverage the experience gained by commercializing SER-109 in the United States to further build our direct sales force to address the larger patient population to be addressed by SER-262. Outside the United States and for chronic diseases in larger populations, we expect to rely on collaborators to commercialize our Ecobiotic microbiome therapeutics.

Developing manufacturing capabilities sufficient to support commercialization of any approved Ecobiotic microbiome therapeutic candidates. If approved by the FDA, we believe SER-109 could be a first-in-field drug, which will require manufacturing capabilities that are distinct from other biologic drugs. We intend to make strategic investments in manufacturing capabilities to help ensure that we maintain control of our know-how and also because we believe these capabilities will be necessary and highly advantageous for the development of future Ecobiotic microbiome therapeutics such as SER-262. Our bioprocess and manufacturing personnel are focused on creating a platform of manufacturing expertise that will set the stage for further advances in the emerging field of microbiome therapeutics.

(Emphasis in original.)

28. Following the Company's June 2015 IPO, on August 6, 2015, Seres issued a press release announcing its first quarter 2015 financial results. In the press release, Defendant Pomerantz emphasized the Company's strategic position with respect to the development of SER-109:

We have made significant progress this quarter to advance our mission of delivering Ecobiotic® microbiome medicines to patients, which we believe will have a strong impact in multiple therapeutic areas. We initiated a Phase 2 study of our lead therapeutic SER-109 and also received Breakthrough Therapy Designation from the FDA for SER-109 – both ***critical milestones as we develop this novel therapy for recurrent Clostridium difficile infection***, or CDI. We completed a successful initial public offering of our common stock, which we believe ***indicates confidence in our science, our team, and our data to date, and gives us a solid financial runway to advance our pipeline and develop additional drug candidates using our microbiome therapeutics platform***. As we look ahead, we are excited to advance clinically with the initiation of a Phase 1 study of SER-287 in ulcerative colitis, and the expansion of our CDI franchise with the initiation of clinical studies of SER-262 to prevent the initial recurrence of C. Diff infection.

(Emphasis added.)

29. Soon thereafter, on August 8, 2015, Seres filed its Form 10-Q Quarterly Report (the “First Quarter 2015 Report”) with the SEC, reporting its first quarter 2015 financial results. The First Quarter 2015 Report repeated many of the false statements found in the Registration Statement and characterized SER-109 as amongst a “novel class of biological drugs” and potential “*first-in-field drug*.” These overtly positive representations continued in Form 10-Q’s, Form 8-K’s, and Company press releases filed or issued throughout the Class Period. Each of these documents were signed and certified as accurate by Defendants Pomerantz and Shaff.

30. For example, on September 30, 2015, the Company filed its Quarterly Report on Form 10-Q for the second quarter 2015 (the “Second Quarter 2015 Report”), in which it similarly characterized SER-109 as amongst a “novel class of biological drugs” and potential “first-in-field drug.”

31. Then, on March 14, 2016, Seres filed its Annual Report on Form 10-K for the 2015 fiscal year ended December 31, 2015 (the “2015 Annual Report”). The 2015 Annual Report emphasized that SER-109 would be a breakthrough therapy for CDI and therefore, insulated from most competition:

We are developing a new approach to treating disease by restoring a dysbiotic colonic microbiome to a healthy state using our Ecobiotic microbiome therapeutics. Our approach is premised on the hypothesis that the proximal cause of many diseases is a dysbiosis in the natural state of the colonic microbiome that perpetuates the conditions that allow disease to take hold and flourish. *We believe that the restoration of a dysbiotic colonic microbiome using rationally designed therapeutics represents a paradigm shift in the approach to treating the underlying disease.* Our Ecobiotic microbiome therapeutics, which are derived from our microbiome therapeutics platform, are rationally designed ecological compositions, consisting of discrete combinations of beneficial microorganisms with targeted functional properties that provide the ability to re-establish keystone features of a functional microbiome in settings of disease. *There are currently no FDA-approved therapeutics that are designed to restore the microbiome to a healthy state.*

Our approach to discovery and design is based on an iterative bedside-to-bench-to-bedside drug discovery strategy that begins with data on the human microbiome that we gather from clinical studies. From these data, we identify the ecological differences between a healthy and a diseased microbiome, which we then use to rationally design potential Ecobiotic microbiome therapeutics. After further in-lab testing, selected Ecobiotic microbiome therapeutic candidates are moved back into the clinic for testing with humans. We apply a comparative genomic systems biology framework that leverages proprietary computation, microbiology and screening capabilities to design lead candidates targeted at these ecological deficiencies.

We are able to apply this framework and experience to existing clinical data sets, as well as to the proprietary clinical data set we have generated through our SER-109 clinical trials. We believe we can utilize our knowledge and data to design Ecobiotic microbiome therapeutics to treat various medical conditions, such as non-Clostridium difficile infection and inflammatory and metabolic diseases. We also have advanced capabilities in the fermentation of colonic bacteria and the formulation of vegetative and spore forms of bacteria into therapeutics. We believe that the combination of experience, proprietary data and proprietary know-how that comprise our microbiome therapeutics platform provides us with a competitive advantage in the design and development of microbiome therapeutics. ***Further, our approach and platform, which enable the rational design, testing, optimization, formulation and manufacturing of Ecobiotic microbiome therapeutics, provide a framework that we believe can significantly reduce the time typically required to advance therapeutics to the clinic.***

(Emphasis added.)

32. The 2015 Annual Report continued on to tout the efficacy of SER-109, stating in relevant part:

We initiated a Phase 2 clinical study of SER-109 for recurrent CDI and dosed the first patient in May 2015. We expect initial study results in the middle of 2016. ***We have conducted manufacturing process pre-validation studies of SER-109 to support a Phase 3 clinical trial and a potential biologics license application and commercial launch.***

We believe the results of our open label Phase 1b/2 clinical study of SER-109 provide validation of the hypothesis underlying our microbiome therapeutics platform, supporting its further use to develop additional Ecobiotic microbiome therapeutics. Using the data we obtained from the SER-109 clinical trial, we are developing SER-262 as an Ecobiotic microbiome therapeutic designed to be used following antibiotic treatment of primary CDI to prevent the initial recurrence of CDI. SER-262 consists of bacteria that are a subset of the bacterial ecology

comprising SER-109. Unlike SER-109, SER-262 strains are clonally isolated and produced in fermenters and do not require sourcing raw materials from human donations. There are several advantages to using a synthetic approach to developing microbiome therapeutics. Synthetically derived product candidates can be scaled up to meet global demand in a reliable reproducible manner, with well-defined characteristics. Based on our metagenomics expertise, proprietary in silico algorithms, world-leading, proprietary bacterial library, and field-leading manufacturing capabilities, we believe we can design synthetically produced microbiome therapeutic candidates for specific target indications. ***Importantly, our unique capabilities provide Seres with a significant competitive advantage in developing synthetically produced microbiome therapies.*** Pre-clinical studies of SER-262 have demonstrated efficacy in preventing the initial recurrence of CDI in mouse and hamster models. We intend to initiate clinical studies of SER-262 in patients with primary CDI to prevent recurrence in the middle of 2016.

(Emphasis added.)

33. At all relevant times, these statements were false and misleading because Defendants were well aware that the Phase 2 clinical trial of SER-109 would fail to achieve its primary endpoint of CDI recurrence as compared to placebo. Specifically, because of the Company's parallel open-label study of SER-109, Seres management was aware that enrollment rates in the parallel study indicated that SER-109 was not performing well in the Phase 2 clinical trial. In addition, Seres management was aware that they had made certain formulation changes to the Phase 2 clinical trial which could affect the clinical cure rate of SER-109. Despite this, Seres management continued to mislead investors regarding the status of the Phase 2 clinical trial, the efficacy of SER-109, and SER-109's attendant likelihood for FDA approval.

The Truth Emerges

34. On July 29, 2016 the Company issued a press release announcing that the Phase 2 clinical trial of SER-109 administered as a single oral dose for the treatment of recurrent CDI did not achieve its primary endpoint when compared to a placebo. Significantly, SER-109 failed to prove that it was even marginally more effective than the placebo, i.e. no treatment at all. The press release stated in pertinent part:

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 29, 2016-- Seres Therapeutics, Inc. (NASDAQ:MCRB), a leading microbiome therapeutics company, today announced interim 8-week results from the ongoing SER-109 Phase 2 ECOSPOR™ clinical study for the prevention of multiply recurrent *Clostridium Difficile* infection (CDI). The study's primary endpoint of reducing the relative risk of CDI recurrence at up to 8-weeks was not achieved. Seres continues to gather and analyze study data, and in consultation with the FDA, plans to make appropriate adjustments to its SER-109 development plans.

Study Design and Results

- Study Design: The Phase 2 study enrolled 89 subjects with multiply recurrent CDI, defined as 3 or more recent recurrences, in a randomized, double-blind, placebo-controlled 24-week study conducted to evaluate the safety and efficacy of SER-109. Subjects were randomized at a 2:1 ratio with 59 subjects receiving SER-109 and 30 subjects receiving placebo. SER-109 was administered orally as a single dose, of 1×10^8 bacterial spores, following the completion of antibiotic treatment for CDI. The study was conducted at 36 centers across the United States. Reported interim results reflect the available eight-week study data, including the primary efficacy endpoint, for the intent-to-treat study population.
- Summary of Efficacy: The predefined study primary efficacy endpoint is the relative risk of CDI recurrence up to 8 weeks after treatment comparing subjects in the placebo arm with the SER-109 arm. CDI recurrence is defined as diarrhea for 2 or more consecutive days, a positive CDI test, and the requirement for antibiotic treatment. ***Based on 8-week data, CDI recurrence occurred in 44% of subjects (26 of 59) who received SER-109, compared to 53% of subjects (16 of 30) who received placebo. The relative risk of CDI recurrence for the placebo population compared to the SER-109 population was not statistically significant.*** As part of the prespecified design, subjects were stratified into two groups: <65 years old and ≥65 years old. In subjects <65 years old, CDI recurrence occurred in 43% of subjects who received SER-109 (12 of 28) and in 27% of subjects who received placebo (4 of 15). In subjects ≥65 years old, CDI recurrence occurred in 45% of subjects who received SER-109 (14 of 31), and in 80% of those who received placebo (12 of 15).
- Summary of Safety: Based on the eight-week data, we did not observe any difference in the adverse event frequency or type in the subjects receiving SER-109 compared to those receiving placebo. The most commonly reported adverse events in both the SER-109 and placebo arms were in the gastrointestinal category. The most common adverse events reported in the SER-109 arm were diarrhea, abdominal pain and flatulence. No drug-related serious adverse events were observed.

(Emphasis added.)

35. In an earnings call with analysts that followed, Defendant Pomerantz disclosed that certain previously undisclosed modifications had been made to the formulation of SER-109 prior to the Phase 2 clinical trial:

Regarding the Phase 2 SER-109 drug product, a few manufacturing and formulation modifications were implemented prior to the study to purify and concentrate SER-109 bacterial spore. We are now seeking to ascertain if any of these changes had an adverse impact on drug product.

...[J]ust to remind everyone *main changes were just on increased concentration, increased purity went from 15 to 30 capsules to four*, all the release facts that we worked out with FDA look good. But clearly when something has a problem in Phase 2, you always look at CMC [Chemistry, manufacturing and control], we are looking at it. We are looking both at the drug in comparison but also as you point out looking at the effects on the microbiome. We have patient samples from every patient before, during and after therapy. We will measure their microbiome using 16S ribosomal as well as shock and sequencing for full genome amount. That will help tell us as well how well the CMC new product work. Because we do have a comparator in 1b where we know the microbiome for each of those 30 patients. And again one of the things I want to remind you that also makes it complex is that we not only didn't hit the primary efficacy endpoint but we had interesting data as we said on the previous call. One is that it worked much better ending greater than 65 and less 65 patients. That's a pre secondary endpoint; it's not something that was done post talk. It was built into the trial. And there was huge placebo effect in the less than 65. *This is somewhat complex data which may or may not be due to CMC or other factors including the clinical trial itself.* So that's what we'll do with CMC. We expect there to be an answer. I always -- when we put a hypothesis out in science, it has to be falsifiable otherwise it is not science. So good thing about all the hypothesis we are generating now is that answers will be obtained.

(Emphasis added.)

36. As a result of the adverse results of the Phase 2 clinical trial of SER-109, the price of Seres common stock declined from a closing share price of \$35.77 on July 28, 2016 to close at \$9.73 per share on August 1, 2016, *a loss of more than 70%*, on extremely heavy trading volume.

ADDITIONAL SCIENTER ALLEGATIONS

37. As alleged herein, Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Seres, their control over, and/or receipt and/or modification of Seres's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Seres, participated in the fraudulent scheme alleged herein.

LOSS CAUSATION

38. During the Class Period, as detailed herein, Defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Seres's securities and operated as a fraud or deceit on Class Period purchasers of Seres's securities by materially misleading the investing public. Later, when Defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of Seres's securities fell precipitously, as the prior artificial inflation came out of the price over time. As a result of their purchases of Seres securities during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

**APPLICATION OF PRESUMPTION OF RELIANCE:
FRAUD-ON-THE-MARKET DOCTRINE**

39. At all relevant times, the market for Seres's securities was an efficient market for the following reasons, among others:

- a) Seres securities met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- b) Seres filed periodic public reports with the SEC and the NASDAQ; and
- c) Seres regularly communicated with public investors via established market communication mechanisms, including regular disseminations of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services.

40. As a result of the foregoing, the market for Seres's securities promptly digested current information regarding Seres from all publicly available sources and reflected such information in the prices of the securities. Under these circumstances, all purchasers of Seres securities during the Class Period suffered similar injury through their purchase of Seres securities at artificially inflated prices and a presumption of reliance applies.

NO SAFE HARBOR

41. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking

statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Seres who knew that the statement was false when made.

CLASS ACTION ALLEGATIONS

42. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Seres securities during the Class Period (the “Class”). Excluded from the Class are Defendants and their families, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

43. The members of the Class are so numerous that joinder of all members is impracticable, since Seres has millions of shares of stock outstanding and because the Company’s shares were actively traded on the NASDAQ. As of March 7, 2016, Seres had more than 39.1 million shares issued and outstanding. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are thousands of members in the proposed Class and that they are geographically dispersed.

44. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members, including:

- (a) whether the Exchange Act was violated by Defendants;
- (b) whether Defendants omitted and/or misrepresented material facts in their publicly disseminated reports, press releases, and statements during the Class Period;
- (c) whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) whether Defendants participated and pursued the fraudulent scheme or course of business complained of herein;
- (e) whether Defendants acted willfully, with knowledge or recklessly in omitting and/or misrepresenting material facts;
- (f) whether the price of Seres securities was artificially inflated during the Class Period as a result of the material nondisclosures and/or misrepresentations complained of herein; and
- (g) whether the members of the Class have sustained damages as a result of the decline in value of Seres's stock when the truth was revealed, and if so, what is the appropriate measure of damages.

45. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct in a substantially identical manner.

46. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

47. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

CLAIMS FOR RELIEF

COUNT I

**Violation of Section 10(b) of
the Exchange Act and SEC Rule 10b-5
(Against All Defendants)**

48. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein.

49. This Count is asserted by Plaintiff on behalf of themselves and the Class against all the Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. C 240.10b-5, promulgated thereunder.

50. During the Class Period, Defendants carried out a plan, scheme, and course of conduct that was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Seres's common stock; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Seres's common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, the Defendants, and each of them, took the actions set forth herein.

51. Defendants, by the use of means and instrumentalities of interstate commerce: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; and (iii) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers and acquirers of the Company's common stock in an effort to maintain artificially high market prices for Seres's common stock in violation of Section 10(b) of the Exchange Act and Rule 10-5.

52. As a result of their making and/or their substantial participation in the creation of affirmative statements and reports to the investing public, Defendants had a duty to promptly disseminate truthful information that would be material to investors in compliance with the integrated disclosure provisions of the SEC, as embodied in SEC Regulation S-K (17 C.F.R. § 229.10, et seq.) and other SEC regulations, including accurate and truthful information with respect to the Company's operations and performance so that the market prices of the Company's publicly traded securities would be based on truthful, complete, and accurate information. Defendants' material misrepresentations and omissions as set forth herein violated that duty.

53. Defendants engaged in the fraudulent activity described above knowingly and intentionally or in such a reckless manner as to constitute willful deceit and fraud upon Plaintiff and the Class. Defendants knowingly or recklessly caused their reports and statements to contain misstatements and omissions of material fact as alleged herein.

54. As a result of Defendants' fraudulent activity, the market price of Seres was artificially inflated during the Class Period.

55. In ignorance of the true financial condition of Seres, Plaintiff and other members of the Class, relying on the integrity of the market and/or on the statements and reports of Seres containing the misleading information, purchased or otherwise acquired Seres's common stock at artificially inflated prices during the Class Period.

56. Plaintiff and the Class's losses were proximately caused by Defendants' active and primary participation in Seres's scheme to defraud the investing public by, among other things, failing to fully and accurately disclose to investors adverse material information regarding the Company. Plaintiff and other members of the Class purchased Seres's stock in

reliance on the integrity of the market price of that common stock, and Defendants manipulated the price of Seres's common stock through their misconduct as described herein. Plaintiff's and the Class's losses were a direct and foreseeable consequence of Defendants' concealment of the true financial condition of Seres.

57. Throughout the Class Period, Defendants were aware of material non-public information concerning Seres fraudulent conduct (including the false and misleading statements described herein). Throughout the Class Period, Defendants willfully and knowingly concealed this adverse information, and Plaintiff's and the Class's losses were the foreseeable consequence of Defendants' concealment of this information.

58. As a direct and proximate cause of the Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their respective purchases and sales of Seres common stock during the Class Period.

COUNT II
Violation of Section 20(a) of the Exchange Act
(Against the Individual Defendants)

59. Plaintiff incorporates by reference and realleges each and every allegation above as though fully set forth herein.

60. During the Class Period, the Individual Defendants were privy to non-public information concerning the Company and its business and operations via access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and Board meetings and committees thereof and via reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew or recklessly disregarded the fact that adverse facts specified herein had not been disclosed to, and were being concealed from,

the investing public. Plaintiff and other members of the Class had no access to such information, which was, and remains solely under the control of the Defendants.

61. The Individual Defendants were involved in drafting, producing, reviewing and/or disseminating the materially false and misleading statements complained of herein. The Individual Defendants were aware (or recklessly disregarded) that materially false and misleading statements were being issued by the Company and nevertheless approved, ratified and/or failed to correct those statements, in violation of federal securities laws. Throughout the Class Period, the Individual Defendants were able to, and did, control the contents of the Company's SEC filings, reports, press releases, and other public statements. The Individual Defendants were provided with copies of, reviewed and approved, and/or signed such filings, reports, releases and other statements prior to or shortly after their issuance and had the ability or opportunity to prevent their issuance or to cause them to be corrected.

62. The Individual Defendants also were able to, and did, directly or indirectly, control the conduct of Seres's business, the information contained in its filings with the SEC, and its public statements. Moreover, the Individual Defendants made or directed the making of affirmative statements to securities analysts and the investing public at large, and participated in meetings and discussions concerning such statements. Because of their positions and access to material non-public information available to them but not the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations that were being made were false and misleading. As a result, the Individual Defendants are responsible for the accuracy of Seres's corporate releases detailed herein and is therefore responsible and liable for the misrepresentations contained herein.

63. The Individual Defendants acted as controlling persons of Seres within the meaning of Section 20(a) of the Exchange Act. By reason of their position with the Company, the Individual Defendants had the power and authority to cause Seres to engage in the wrongful conduct complained of herein. The Individual Defendants controlled Seres and all of its employees. As alleged above, Seres is a primary violator of Section 10(b) of the Exchange Act and SEC Rule 10b-5. By reason of their conduct, the Individual Defendants are liable pursuant to section 20(a) of the Exchange Act.

64. As a direct and proximate result of the wrongful conduct of Seres and the Individual Defendants, Plaintiff and members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment as follows:

(A) Declaring this action to be a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure and certifying Plaintiff as a representative of the Class and her counsel as Class counsel;

(B) Awarding Plaintiff and the members of the Class damages, including interest;

(C) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including and attorneys' fees; and

(D) Awarding such equitable/injunctive or other relief as the Court may deem just and proper

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: September 28, 2016

/s/ Shannon L. Hopkins

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